U.S. Department of Commerce Conformity Assessment Roundtable (11/7/2003)

CIL, the National Institute of Standards and Technology (NIST), and the Department of Commerce's Technology Administration hosted a Roundtable on Conformity Assessment on October 30, 2003 from 1:00 pm until 3:30 pm in the Herbert C Hoover Building Room 6029. Walter Poggi, President, Retlif Laboratories and Chairman of the ACIL Government Relations Committee, moderated the Roundtable.

Mr. Poggi noted that the conformity assessment industry IS an industry and must be viewed as such. Conformity assessment provides the means for a manufacturer or distributor to move goods into an intended market. Comparing the conformity assessment industry to the transportation industry, Mr. Poggi noted that the conformity assessment industry's test reports, or inspection, or certification marks can be viewed as "vehicles" that provide the access needed to enter most national and international market. However, while the conformity assessment industry is vital to the manufacturing industry, they are not part of it. The issues of the conformity assessment industry are different from the manufacturing industry. The laboratory community, for example, wants one accreditation to one standard accepted worldwide. It is concerned about the lack of coordination in the accreditation area. The growth of private sector accreditation programs, which then become marketplace requirements, is uncontrolled. Companies like Verizon see a need to develop and administer an accreditation program and do so. It is unclear how such programs affect trade, or existing/developing Mutual Recognition Agreements (MRAs) or other trade agreements. Mr. Poggi also discussed MRAs, noting that the MRA process has not only been good for his laboratory, it also has caused beneficial changes in the operations of some government agencies, such as the Federal Communications Commission. However, the MRA process is NOT the only approach. MRA's, supplier's declaration of conformity (SDOC), and national treatment are all "trade tools" that should be on the table in all trade negotiations. The issue is not which approach should be used, but ensuring about fairness and openness. It is about allowing small to medium size U.S. conformity assessment organizations that support small to medium size U.S. manufacturers to gain acceptance of results of their conformity assessments in international markets so that those manufacturers have access to the markets.

After opening remarks by Mr. Poggi, Deputy Under Secretary (D/US) for Technology Administration (TA) Benjamin Wu welcomed the guests and speakers and provided a summary of Secretary Evans Eight-Point Standards Initiative. D/US Wu also outlined the standards-related work being done by the Department's National Institute of Standards and Technology (NIST) and the International Trade Administration (ITA) to reduce barriers to trade.

Following D/US Wu's remarks, representatives from various trade associations made the following points:

The Air-Conditioning and Refrigeration Institute (ARI)
Jim Walters, Director, International Standards, ARI

ARI is a not-for-profit trade association in Arlington, VA. It has 210 member companies that comprise about 90% of the manufacturers of central air conditioning and refrigeration equipment

in North America. ARI represents a global industry that sees standards and certification as business tools with positive societal benefits. ARI holds the Secretariat of two International Organization for Standardization (ISO) subcommittees and also holds the Chair and Secretariat of a U.S. ISO Technical Advisory Group (TAG). ARI chairs a U.S. International Electrotechnical Commission (IEC) TAG and a Council for Harmonization of Electrotechnical Standards of the Nations of the Americas (CANENA) TAG. ARI wants to provide consumers with confidence regarding the products they purchase, provide a level playing field for manufacturers, and facilitate compliance to federal, state, and local government minimum energy efficiency standards. ARI operates 25 product specific performance programs that verify manufacturers' energy efficiency ratings via an extensive 3rd party testing scheme. It uses recognized industry test standards and is open to foreign and domestic manufacturers, ARI members and nonmember alike. ARI's certification program operates in full compliance with Canada's energy efficiency regulations and is accredited by Standards Council of Canada (SCC). ARI's program is also recognized by National Resources Canada (NRCan). ARI has provided "how to" advice for mirror program in China, the Gulf States, and India and has established mutual recognition agreements with counterparts in Europe and Canada.

Specific Issues of Concern:
· There is a lack of global harmonization regarding certification program requirements.
· Regional or country imposed "new" schemes, such as the one based on the European Union's (EU) pressure equipment directive, can hurt U.S. certification organizations and U.S. manufacturers.
· The impact of China's new "CCC" mark is unknown and may be a problem for U.S. conformity assessment bodies and U.S. industry.
· Compliance with WTO requirements encourages countries not to adopt non-ISO standards, such as those of ARI and the American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. (ASHRAE), and negatively impacts certification programs that are based on such standards.
· Not being involved in the creation of country conformity assessment requirements and schemes due to the lack of local intelligence can result in foreign requirements and conformity assessment programs that negatively impact both manufacturers and conformity assessment organizations.

Desired Government Assistance:
· Need the USG to focus on gathering and providing early market intelligence to U.S. industry.

National Electrical Manufacturers Association (NEMA)
Jim Cigler, Manager, Conformity Assessment Programs, NEMA

NEMA is the largest trade association representing the interests of U.S. electrical industry manufacturers, whose worldwide annual sales of electrical products exceed $120 billion. Its mission is to improve the competitiveness of member companies by providing high quality services that impact positively on standards, government regulation and market economies. NEMA's more than 4000 member companies manufacture products used in the generation, transmission, distribution, control and use of electricity. These products are mostly unregulated, are used in utility, industrial, commercial, institutional and residential installations. The

Association's Medical Products Division represents manufacturers of medical diagnostic imaging equipment including MRI, CT, x-ray, ultrasound and nuclear products. With the support of the Commerce Department Market Development Cooperator Program (MDCP), NEMA has opened Mexican and Brazilian offices that have successfully addressed standards and conformity assessment issues in those two countries. NEMA has just been awarded a new MDCP grant to open an additional office in Beijing China which will help gain a better understanding of the standardization and conformity assessment processes in that country.

Specific Issues of Concern:

· Conformity assessment policies and practices are having a growing impact on global commerce and can either facilitate or impede international trade. It is imperative that U.S. industry is kept current on country-specific processes by which products are certified and approved for placement on the market.

· There must be an understanding and recognition of the conformity assessment needs of each industrial sector. Conformity assessment requirements will vary by industry and should be based on marketplace needs.

· IEC's global relevance initiative is important and should be encouraged. It is aimed at having IEC standards that can accommodate essential differences in requirements to meet the needs of major segments of the international market.

· The EU continues to seek New Approach Directives such as those relating to Chemicals and Environmentally-Friendly-End-Use-Products (EuP) that would negatively impact U.S. manufacturers' products in varying ways. In the case of the chemicals proposal, it has significant implications for downstream users. The EU is establishing such regulations with questionable technical justification. Compliance costs are often not proportionate to intended consumer or environmental benefits.

· CEN and CENELEC lack transparency and openness as they, per the New Approach process, develop standards when there is specific prior knowledge that the resulting standards will be incorporated into the EU's regulatory process.

· While Beijing has committed to change its conformity assessment procedures to accord non-Chinese products "national treatment," for many electrical products, it has also recently made moves to only accept goods built to either Chinese national standards or standards published by the IEC and ISO. ISO and IEC standards often do not include products built to North American-based requirements.

· While Mexican authorities do accept and take into account public comments on proposed mandatory standards, a document that has been substantially revised based on public comment may not be circulated for final public review prior to publication. The Mexican standard's authority should apply consistent procedures in the consideration and adoption of mandatory NOM standards.

· Mexico's indication that it will recognize U.S. and Canadian conformity assessment bodies only when it is determined that additional conformity assessment capability is needed in Mexico does not meet the intent of Mexico's obligations under NAFTA. It should be noted that this situation might be improving, as one US certification body has applied for recognition by the Mexican government.

· To assist its domestic producers, Argentina continues to revise its conformity assessment requirements without transparency and particularly without advance notice. Uruguay has also begun embarking on a similar path, adopting comparable requirements without prior public

notice or public participation.
· The U.S. standard covering power cords requires that the cord be labeled to indicate the power handling capacity in terms of the operating voltage and current carrying capacity. The Brazilian standard requires that the plug at the end of the cord be labeled in a similar manner. This prevents the power cords made to the U.S. standard from being exported to Brazil and vice versa. Due to the long time that it takes to harmonize standards, the manufacturer is faced with building differently marked power cords that he wishes to sell in this country and Brazil. This amounts to additional engineering and production time and expense.
· An IEC standard for limitations on the amount of harmonic current that may be emitted by electrical equipment has been adopted as regulation within Europe. NEMA believes that the levels imposed on most equipment were overly stringent on the basis that the actual utility line harmonic currents were significantly below the susceptibility level imposed on connected equipment. Thus there is no need for manufacturers to make significant and expensive modifications to their equipment. In addition, the adoption of the IEC document as a regulation was done without any general input or opportunity for comment. This prevented the US interests from being presented or discussed and thus led to the implementation of overly severe requirements.
· China requires that all products requiring mandatory certification must be tested and certified by Chinese testing and certification bodies. It is hope that this policy will change.
· The HAR Agreement is a private sector harmonization agreement in which European manufacturers have agreed to test electrical cables according to the European standards (EN standards) and grant the use of the HAR mark on those products. Sales of cables in Europe without the HAR mark are significantly less than for those carrying it. Countries outside of Europe may now participate in the HAR agreement only by rescinding their national standards in favor of the EN standards. There is not justification for this requirement.
· In recent years, Japan has issued regulations on certification requirements, metric-only labeling, and product waste take-back. Often a technical regulation enters into force before a final text of the regulation is available from the government. The 2001 WTO Ministerial in Doha clarified that under the TBT, the "reasonable interval" countries must give each other at least six months between the publication of new technical regulations and entry-into-force, except in emergency cases. Japan needs to adhere to the WTO TBT requirements for justification, notice and comment on technical regulations.
· The Global Relevance program for the development of IEC standards will create a mechanism whereby the essential differences which result from a country's infrastructure requirements (power grid voltages and frequencies, national electrical code requirements) or climatic differences can be included as part of the standards' development process and agreed to by the international community. However, it is doubtful that there will be an equivalent harmonization on the types of conformity assessment employed in making the compliance determination as it is expected that countries and regions will continue to operate in accordance with the market driven needs of each sector and applicable regulatory and governance requirements.

Desired Government Assistance:
· To work with industry and trade associations to engage the EU on questions of governance and regulatory discipline; to find solutions for regulatory problems with the EU; and to ensure justification, transparency and openness in the development of directives, as well as "national treatment" and accountability in their application.

· To continue to urge China as a new member of the WTO to improve its transparency and information sharing regarding its standards development and conformity assessment requirements for electrical products.
· While many APEC governments continue to pursue the development of a public sector Mutual Recognition Arrangement on Conformity Assessment of Electrical and Electronic Equipment, NEMA is pleased that the U.S. government has not participated. It is more productive to first pursue the potential for a private sector conformity assessment system that allows for National Treatment of foreign testing bodies and cooperative testing agreements between testing bodies in different countries. As stated in NEMA's Position on Conformity Assessment, while NEMA is in favor of public sector MRAs for federally regulated products such as medical devices, it opposes them for non-regulated items such as most other electrical equipment.
· U.S. negotiators need to call on countries to afford national treatment to all products, as well as transparency in the development of conformity assessment requirements. U.S. negotiators have emphasized addressing these kinds of practices in the recently established US-MERCOSUR "Four-plus-One" dialogue
· There should be an effort on the part of the IEC and/or the U.S. government to pursue the implementation of a policy to address the following:
- International standards organizations need a process where standards with regulatory implications are exposed in some formal way to an international forum of the regulators that may use them.
- International standards developers require a 'justification' section for each standard that establishes the market need, discusses economic alternatives, and defines the criteria demonstrating relevance.
· Examples of where the USG has effectively addressed standards and conformity assessment issues and should continue to do so include:
- Insistence that OSHA retain authority over its Nationally-Recognized Testing Laboratory (NRTL) accreditation, leading to the European Union's withdrawal from the electrical safety annex of the U.S.-E.U mutual recognition agreement.
- The USG's refusal to sign any new government-to-government MRA's involving unregulated electrical products, the latest example being the Free Trade Agreement with Singapore.
- Advocacy leading to China's acceptance that it would need to grant conformity assessment "national treatment" in conjunction with its WTO accession. This has led to the new China Compulsory Certification (CCC) mark, as well as a revamping of its standards and conformity assessment bodies.
- Advocacy leading up to language on "international standards" in the Second WTO TBT Triennial Review. The agreed-upon statement and annex called for the open, transparent development of relevant, science-based standards that respond to regulatory and market needs. "In addition, they should not give preference to the characteristics or requirements of specific countries or regions when different needs or interests exist in other countries or regions."
- Advocacy leading to the withdrawal of the EU-country-of-origin requirement from the European Union's Protocols on Conformity Assessment (PECAs) for Eastern European countries that are on track to becoming members.
- Commerce Department assistance relating to obtaining Measurement Law of Japan requirements and its helping to determine that the requirements would likely not pose an undue hindrance to U.S. industry.
· The Department should carry the message that standards developed under the principles set

forth by ANSI are consistent with the openness and transparency objectives set forth by the WTO TBT guidelines, and that countries that choose to adopt U.S. based standards as their national standards are not in conflict with WTO provisions.
· The U.S. should continue to promote the concept that ISO and IEC standards must be "inclusive" of practices and standards with broad multinational acceptance and should accommodate essential differences to meet international market needs.
· Standards harmonization, where appropriate for the market sector needs, must be pursued in a manner that reflects the principles of the WTO TBT Agreement. Harmonization of existing standards does not always necessitate identical standards, but rather a set of mutually "equivalent and compatible" inclusive standards, with as few national differences as possible. The development of national differences, when necessary, must be transparent and those differences must be included in the international standard.
· Standards should be developed by the private sector, with the government participating in the standards development processes. The marketplace should choose the applicable product standards and the conformity assessment process.
· Only when health, safety, or environmental standards and conformity assessment needs cannot be met by the private sector should government regulations be considered.
· USG should discourage the proliferation of standards, which may spawn a new generation of conformity assessment activities on the part of manufacturers, certification bodies and accreditation bodies, such as development of standards related to corporate or organizational social responsibility, market-based codes of conduct, and European initiatives such as development of New Approach Directives related to Chemicals, Environmentally-Friendly-End-Use-Products (EuP), and Waste Electrical and Electronic Equipment (WEE).

U.S. Gypsum (USG)
Robert Bell, Director, Government Affairs, USG

USG is a $3.5 billion Fortune 500 company that is a leading manufacturer of building materials for the construction and remodeling industries. For more than 100 years, Chicago-based USG has produced products are used in everything from major commercial developments and residential housing to simple home improvement projects. USG is the world's leading producer of gypsum wallboard, joint compound and a vast array of related construction products. USG is also a global leader in the manufacture of ceiling suspension systems and are recognized as the acoustical panel and specialty ceiling systems innovator.

USG, through its subsidiary L&W Supply, is also the nation's largest distributor of drywall and related building products. L&W serves the professional contractor through a network of nearly 200 locations and strives to be their preferred source for all quality products and services they need to complete their projects on time and on budget.

USG has 14,000 employees working in over 30 countries. USG flagship brands include SHEETROCK® gypsum panels and DUROCK® cement board, which are recognized around the world.

Specific Issues of Concern:
· Arbitrary national certification programs can exclude company products from the marketplace, i.e., Taiwan's disqualification of U.S. acoustical ceiling tile.
· Arbitrary product requirements, such as size requirements in Brazil, can also impede competitiveness of U.S. companies.
· It is often too expensive for companies to fight such requirements. Often easier to just concentrate on profitable markets.

Desired Government Assistance:
· Continued assistance in resolving trade-related problems.
· Early intelligence on changes in product and conformity assessment requirements.

Underwriters Laboratories (UL)
Gordon Gillerman, Manager, Governmental Services, and Ann Weeks, Manager, International Affairs, UL

Underwriters Laboratories Inc. (UL) is an independent, not-for-profit product-safety testing and certification organization that has tested products for public safety for more than a century. Founded in 1894, UL has earned a reputation as a global leader in product-safety standards development, testing and certification. UL has evaluated thousands of products, components, materials and systems for compliance to specific requirements. UL's time-tested system supports government product safety regulations; and it complements federal, state and local government agencies' public safety initiatives. UL's certification services include testing, evaluation, and factory surveillance of products to UL's standards for safety or other safety requirements. UL has developed more than 800 standards for safety that play an important part in improving public safety. UL is also committed to providing expert management system registration, assessment and audit services to internationally recognized standards, such as those of ISO. In addition, UL provides worldwide supply chain services, including commercial inspection, testing, and auditing services to customer-defined requirements for many types of products and services. These range from manufactured household appliances and electrical goods, building and construction materials to tools and toys.

Specific Issues of Concern:
· Lack of consistent national treatment for conformity assessment organization across all foreign markets. National treatment enables conformity assessment bodies in one country to provide testing and certification to another country's requirements by being recognized or accredited through the same process as is used for domestic bodies. UL believes that national treatment for conformity assessment is the most effective approach to eliminating many trade barriers. National treatment would enable UL and other conformity assessment bodies to provide customers with a seamless certification program where services are bundled and streamlined to facilitate timely effective access for manufacturers.
· Government-to-government MRAs have been largely ineffective in providing market access for U.S. conformity assessment bodies and have reduced attention on national treatment as a conformity assessment solution. Negotiations for the US-EU MRA lasted more that six years, and the confidence-building phase over three years, with only two of the six sectoral annexes

operational and at least one annex suspended. For all this effort, only a handful of products have utilized the MRA.
· National treatment provisions in the Free Trade Agreements to date have lacked comprehensive national treatment provisions that would eliminate loopholes to allow non-compliance.
· National treatment-related problems occur in multiples region, most notably in Europe, China and Mexico.
· UL applied to the Mexican accreditation body (EMA) on September 2nd for accreditation and became the first non-Mexican certifier that UL knows of to apply for accreditation. By the end of November, it should be clear at to whether Mexican authorities will honor their NAFTA obligations.
· In China, foreign certification organizations are not permitted to engage in testing and certification services for the domestic market (the CCC Mark). China's World Trade Organization (WTO) services schedule contains obligations regarding testing and analytical services by foreign enterprises, but leaves unclear whether that includes certification for the domestic market.
· In Europe, the New Approach inherently lacks national treatment for conformity assessment organizations. Under the New Approach, member states are responsible for notification of notified bodies and may only notify bodies within their territory. Therefore U.S. conformity assessment organizations cannot provide cross-border conformity assessment services in the European system.

Desired Government Assistance:
· DOC and the USTR should engage conformity assessment organizations on a more routine basis in their activities related to free trade agreement negotiations and the Technical Barriers to Trade (TBT) Chapters of the WTO Agreement.
· Press China to include certification for the domestic market with in the scope of their services schedule. Ensure that China adopts a broad definition of what constitutes testing and analytical services under its WTO services commitments to include testing/certification for the domestic marker.
· Closely monitor and report on the issuance of new PRC regulations that affect U.S. conformity assessment organizations' ability to offer certification services in China.
· Continue efforts to improve the knowledge base of NIST standards attaches and FCS officials on standards and conformity assessment concepts and industry/country/regional issues. UL would like to assist in these efforts.
· Continue to offer SIT/SABIT workshops to educate foreign government officials on the U.S. standards and conformity assessment system and to build bridges for future cooperation. These broad and specific programs are especially important when they target countries/regions in which standards and conformity assessment systems/structures currently do not exit or are in their infancy and where there is a perceived receptivity to U.S. principles and practices.
· Continue funding for standards and conformity assessment related programs under DOC's Commercial Law Development Program (CLDP).

Intertek Testing Services (ITS)
Joan Sterling, Director, Government Affairs

Intertek is a leading international testing, inspection and certification organization which assesses customers' products and commodities against a wide range of safety, regulatory, quality and performance standards; and, in some cases, certifies the management systems of customers. Intertek has over 250 laboratories with more than 10,000 people around the world and is increasingly undertaking outsourced testing work for its customers

Specific Issues of Concern:
· The European Commission (EC) was to nominate European Union (EU) Conformity Assessment Bodies (CABs) to the U.S. Food and Drug Administration (FDA). FDA was to evaluate and accredit European CABs. Currently 4 EU CABs have completed joint audits with FDA and are recognized by the FDA. FDA was to nominate CABs to the EC, which would evaluate and accredit the U.S. CABs. The extended transition date is nearly complete, and there are still no U.S. CABs recognized by the EC. Six U.S. CABs have applied for recognition. Because FDA has completed its part of the agreement, but the EU has not, there is a disparity, which benefits the EU CABs and EU manufacturers over U.S. organizations.
· The original MRA included more classes of medical devices that are currently being addressed in this process by the EC.
· FDA is contemplating allowing already accredited EU CABs to provide inspections that U.S. CABs cannot provide.
· SCC has already accredited U.S. CABs to provide services to Health Canada, another example of how National Treatment is much more efficient than MRAs.
· It is difficult for U.S. CABS to involve manufacturers n join audits in the U.S. (for EU requirements) due to the fact that the FDA has stated that if it finds violations of U.S> requirements during such audits, it will take action against the manufacturers. This would not occur under National Treatment where EU accreditors would audit U.S. CABs for competence to EU requirements.

Desired Government Assistance:
· The USG needs to push the EC to meeting its obligations under the MRA.
· The U.S. government needs to stress national treatment as possibly a more efficient solution than MRAs.

Discussion/Comments

The discussion at the end of the presentations stressed that conformity assessment was not only an industry in itself; it is also the gateway for the manufacturing industry into the international marketplace. It is therefore crucial that the concerns of the conformity assessment industry be recognized and addressed. Nations should be required to comply with their obligations under the WTO Technical Barriers to Trade (TBT) Agreement whose principles are elucidated in ANSI's National Conformity Assessment Principles for the United States.

The USG also needs to use all tools, not just MRA's in resolving conformity assessment related problems. The US-EU MRA has really only been useful to U.S. industry in the EMC and telecom areas. National treatment provisions should be included in trade agreements and

enforced. Only in Canada are national treatment requirements being implemented effectively. Mexico needs to be encouraged to do likewise.

China remains a major concern because of the potential size of the market.

It was also noted that it is unacceptable that the U.S. and Luxembourg have the same level of voting rights (one vote) in ISO given the size of the U.S. market compared with that of Luxembourg. The voting process in ISO needs to be restructured.